


IP Issues for Combination Products at the Intersection of Nanotechnology and Medical Devices

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IP Asset Life Cycle



Copyrights
Trademarks
Trade Secrets
Patents
Licensing

Problems can arise anywhere in the life cycle

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Significant Problems for Combination Products

- Excluding all competitors for your combination product
- Excluding the manufacturers of separate components of your combination product
- Avoiding statements damaging to your position at the FDA
- Avoiding infringement by the various components of your combination product
- Ensuring that you do not induce or contribute to infringement when providing only a portion of a patented combination product

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Your Patents

- Patent claims should be drafted with the goal of blocking all competitors, not just direct competitors
- Example: The patent's claims cover a device combined with a specific biologic
 - A competitor might avoid infringement by switching to a different biologic
 - Ideally, include all alternative biologics in the original patent
 - If the alternative biologic was not known at the time of the initial patent filing, the applicant should use multiple “continuation-in-part” applications to protect the new biologics as they are discovered
 - Currently, the USPTO allows the filing of an unlimited number of continuing applications; a proposed rule change, however, would impose strict limits

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Your Patents (cont.)

- Patent claims should be drafted with the goal of blocking the *manufacturers* who supply the separate *components* of the combination product – not just the doctors or patients who administer the combined, final product
- Example: The patent covers only the final combination of a drug, a device, and a biologic
 - Manufacturer may escape direct infringement by supplying only the drug and biologic components
 - The doctor or patient will be the only direct infringer when he or she incorporates the device component supplied by a third party

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Patenting and FDA Interface

- Patent application should be filed before applying for FDA approval
- Keep FDA counsel involved with relevant IP portfolio strategy
- Example: Patent application typically does not need to speculate about the invention's primary mode of action
 - Can limit options when working with FDA, such as FDA Center assignment

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Infringement Issues

- Companies selling combination products must coordinate with IP counsel to avoid infringing other parties' patents
- Likelihood of infringement increases with each additional component of the combination product
 - A seller of combination products must have freedom-to-operate for each separate component (i.e., drug, device, biologic) before it can sell the combination

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Infringement Issues (cont.)

- Manufacturer might need permission from multiple parties in vastly different fields
 - Example: Manufacturer might need a separate license agreement with:
 - Large pharmaceutical company for the drug component
 - Microelectromechanical system (MEMS) company for the device component
 - Biotech startup for the biologic component

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Infringement Issues (cont.)

- These three companies likely will differ in a variety of areas:
 - Business interests
 - Sophistication
 - Perceived importance of their patents
- Manufacturer may wish to seek an “anti-stacking” provision that caps the net royalties paid to all patent holders

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Infringement Issues (cont.)

- Marketing must coordinate with IP counsel to avoid infringement
- Inducement
 - “Whoever actively induces infringement of a patent shall be liable as an infringer.”
35 U.S.C. 271(b)

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Infringement Issues (cont.)

- Example
 - Much of the value of a company's device is its use in a final application (e.g., combination product or method), which is patented
 - Company is not selling the final application
 - Company's marketing materials instruct others to make or use the final application

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Infringement Issues (cont.)

- Companies selling components of a combination product must coordinate with IP counsel to avoid infringement
- Contributory Infringement
 - “Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, *knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use*, shall be liable as a contributory infringer.” 35 U.S.C. 271(c)

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Conclusions

- Combination products provide unique IP concerns
- Often these concerns can be adequately addressed through early and continued consultation with IP counsel

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